

STATE OF CALIFORNIA  
FISH AND GAME COMMISSION  
FINAL STATEMENT OF REASONS FOR REGULATORY ACTION

Add new Section 1.92, add new subsection (11) of Section 671(c), and add new  
subsection (9) of Section 671.1(a)  
Title 14, California Code of Regulations

Re: Define the term Transgenic, add transgenic aquatic animals to the list of live  
animals restricted for importation, transportation and possession, and add conditions for  
issuing permits for transgenic aquatic animals.

I. Date of Initial Statement of Reasons: November 4, 2002  
Date of Amended Initial Statement of Reasons: November 26, 2002

II. Date of Pre-adoption Statement of Reasons: January 7, 2003

III. Date of Final Statement of Reasons: February 20, 2003

IV. Dates and Locations of Scheduled Hearings:

(a) Notice Hearing: Date: October 25, 2002  
Location: Crescent City

(b) Discussion Hearing: Date: December 5, 2002  
Location: Monterey

(c) Adoption Hearing: Date: February 7, 2003  
Location: Sacramento

V. Update:

The Commission received testimony on December 5, 2002, that recommended those research projects possessing transgenic fish species under a federal permit be granted an expedited or exempted permit from the Department. In response to this testimony, the Department recommended the addition of a subsection in the terms and conditions that provides for consideration of a federal permit, if the federal permit meets or exceeds State requirements. The purpose of recognizing a federal permitted operation is to avoid redundant evaluation and expedite the permitting process, and provide bona fide researchers some predictability for expecting acceptance of their permit request, where appropriate.

VI. Summary of Primary Considerations Raised in Support of or Opposition to the Proposed Actions and reasons for Rejecting those Considerations.

1. **Karen Reyna, Ocean Conservancy, and National Resources Defense Council, 2/7/03; Justin Malan, California Aquaculture Association, 2/7/03; Claudia Reed, University of California, 2/7/03, Mark Aryens, University of California, 2/7/03.**

Supported proposal and recommended adoption. Reyna and Malan also recommended that future consideration be given to adoption of additional regulatory language requiring review of permit applications in a public forum, and an annual review process of the implementation of the regulation.

**Department Analysis:** The Department concurs with these comments and supports the addition of transparency permit review and an annual review.

2. **Senator Byron Sher, 1/27/03 (letter); Zeke Grader, Pacific Coast Fisherman's Federation Association, 2/7/03; Virginia Handley, Fund for Animals, 2/7/03.**

Opposed to adoption of proposed change in its current form. Supported definition and inclusion of transgenic fish to list of restricted species, however, opposed to use of transgenic fish for commercial purposes or by the pet industry. Sher and Grader also opposed to regulation because it lacked transparency requirement that provides for public notice and review of specific permit applications.

**Department Analysis:** The Department recognizes the need to add additional public notice/review of transgenic permit applications, and annual reporting requirements of implementing transgenic restrictions in regulatory language. The Department also believes that adoption of the proposal in its current form will create a high degree of environmental protection from unwanted transgenic species where such protection presently does not exist in regulations.

3. **Paul Weakland, 2/7/03.**

Opposed to regulation. Does not believe research or any use of transgenic species is necessary.

**Department Analysis:** The Department believes that carefully controlled transgenic related research may yield potential benefits and adoption of the proposal in its current form will create a high degree of environmental protection from unwanted transgenic species where none presently exists.

VII. Location and Index of Rulemaking File:

A rulemaking file with attached file index is maintained at:

California Fish and Game Commission  
1416 Ninth Street  
Sacramento, CA 95814

VIII. Location of Department Files:

Department of Fish and Game  
1416 Ninth Street  
Sacramento, CA 95814

IX. Description of reasonable Alternatives to Regulatory Action:

(a) Alternatives to Regulation Action:

1. **Establish a moratorium on the importation or possession of all live transgenic aquatic animals within the State for an indefinite period.** A moratorium on the importation or possession of transgenic aquatic animals would ensure the protection of natural aquatic animal populations within the State. However, a moratorium is considered too restrictive and would prevent research and the subsequent discovery of potential benefits or adverse impacts that transgenic species may provide.

(b) No Change Alternative: Continue to rely on the Department's guidelines for restricting or permitting the importation of live transgenic aquatic animals, and the approval of these animals for maintenance at registered aquaculture facilities. Current regulations do not specifically identify or restrict transgenic aquatic animals.

(c) Consideration of Alternatives: In view of the current information, no reasonable alternative would be more effective than the purposes for which the regulation is proposed or would be as effective and less burdensome to the affected parties than the proposed regulation.

X. Impact of Regulatory Action:

The potential for significant statewide adverse economic impacts that might result from the proposed regulatory action has been assessed, and the following determinations relative to the required statutory categories have been made:

- (a) Significant Statewide Adverse Economic Impact Directly Affecting Businesses, Including the Ability of California Businesses to Compete with Businesses in Other States: The proposed action will not have a significant statewide adverse economic impact affecting businesses, including the ability of California businesses to compete with businesses in other states.
- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California: None.
- (c) Cost Impacts on a Representative Private Person or Business: The agency is not aware of any significant cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. A permit application will be required for any activity using transgenic fish, but the regulation includes an expedited process for activities operating under a federal permit. The permit application process for other activities using transgenic fish where the evaluation of environmental risk requires extensive evaluations may increase the applicant's initial cost to an unknown degree.
- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.
- (e) Nondiscretionary Costs/Savings to Local Agencies: None.
- (f) Programs Mandated on Local Agencies or School Districts: None.

## **Updated Informative Digest/Policy Statement Overview**

Transgenic species are an example of bioengineered products that are produced under artificial conditions with the goal of enhancing yield or some other economically important biological trait. Transgenic manipulation involves transferring genetic material (DNA) from one organism into chromosomes of another (generally species to species). The resulting genetic makeup of transgenic organisms is unique and these organisms have no genetic counterparts in natural systems. Because of their novel genetic structure, transgenic species should be considered “non-indigenous”, and potentially detrimental to native species.

In view of the increasing interest and concern relative to transgenic animals, the Department recommends that transgenic fish be added, as a general category, to the Commission’s list of restricted species in Section 671, Title 14, CCR. In addition, it is recommended that the terms and conditions for which the Department may issue a permit for transgenic aquatic animals be added to Section 671.1(a).

Permit terms and conditions center around containment of transgenic animals within secure facilities and prevention of their escape or placement into waters of the State. Permit authorization will be based on review of applications, including site inspections when required, to ensure that building configuration, plumbing, and security methods of each facility that may hold transgenic animals, are adequate to provide appropriate containment.

**The Commission subsequently received testimony on December 5, 2002, that recommended those research projects possessing transgenic fish species under a federal permit be granted an expedited or exempted permit from the Department. In response to this testimony, the Department is recommending the addition of a subsection in the terms and conditions that provides for consideration of a federal permit, if the federal permit meets or exceeds State requirements. The purpose of recognizing a federal permitted operation is to avoid redundant evaluation and expedite the permitting process, and provide bona fide researchers some predictability for expecting acceptance of their permit request, where appropriate.**

**Section 1.92, Title 14, California Code of Regulations is added to read:**

Section 1.92 Transgenic

Genetically altered by introducing DNA 1) from another species or 2) through engineered endogenous constructs by means such as but not limited to recombinant DNA and RNA techniques to produce, gene addition, deletion, and doubling, or changing the position of the gene. This definition excludes DNA vaccines, individuals produced by the techniques of whole genome ploidy manipulation, and hybridization between closely related species, as in traditional hybridization.

NOTE

Authority cited: Sections 200, 202, 205, 210 and 220.

Reference cited: Sections 200-202, 205, 206, 210 and 220.

**Subsection (c)(11) of Section 671, Title 14, California Code of Regulations is added to read:**

(11) Transgenic Aquatic Animals.

Includes freshwater and marine fishes, invertebrates, crustaceans, mollusks, amphibians, and reptiles (D).

Note: Unpermitted transgenic aquatic animals are determined to be detrimental to native wildlife, therefore the exemption provided for in Fish and Game Code Section 2150(e) is not applicable.

NOTE

Authority cited: Sections 2118 and 2120, Fish and Game Code.

Reference: Sections 1002, 2116, 2118, 2118.2, 2118.4, 2119-2155, 2190, 2271, 3005.9 and 3005.92, Fish and Game Code.

**Subsection (a)(9) of Section 671.1, Title 14, California Code of Regulations is added to read:**

(9) Transgenic Aquatic Animals. The department may issue permits for importation, possession, transportation or rearing of, or research on, transgenic aquatic animals pursuant to the following terms and conditions:

(A) All transgenic aquatic animals shall be held, raised, and transported in a closed-water system or in a system which treats effluent discharge from the facility with a disinfection system adequate to ensure against the inadvertent release of live animals. A closed-water system means that there is no discharge to waters of the state. Municipal treated sewage systems are not considered waters of the state. The Commission may grant an exception to subsection (a)(9)(A) of this regulation if it is determined that doing so shall not pose a significant risk to the waters or wildlife of the state.

(B) Access to facilities containing transgenic aquatic animals must be restricted through means determined to be adequate by the Department to assure against unauthorized removal of animals.

(C) Movement of live transgenic aquatic animals from facilities is prohibited unless specifically permitted by the Department.

(D) Release of transgenic aquatic animals or their progeny into waters of the state is prohibited.

(E) If transgenic aquatic animals are held with non-transgenic animals of the same species, all such animals that commingle with transgenic animals shall be treated as transgenic for the purposes of regulation and may not be introduced into waters of the state. Nontransgenic individuals that can be individually identified as nontransgenic may be exempt from this provision with prior department approval.

(F) In addition to any other penalty provided by law, any unauthorized release of transgenic aquatic animals or their progeny into the waters of the state may be subject to the penalties provided for under Fish and Game Code Sections 2125, 12007, and/or 12023

(G) A university, college, governmental research agency or other bona fide scientific institution, as determined by the department, may apply for an expedited permit review under 671(b)6 of this section by demonstrating that they meet or exceed the requirements stipulated in subsections (A) through (F) as part of a federal program or permit, for example, National Institute of Health guidelines administered by an Institutional Animal Care and Use Committee (IACUC). Such institutions shall have 120 calendar days from May 14, 2003 to submit supporting documentation for an initial permit.

#### NOTE

Authority: Sections 1002, 2118, 2120, 2122, 2150, and 2150.2, Fish and Game Code.

Reference: Sections 2116-2118, 2190, and 2271, Fish and Game Code.